

AperTO - Archivio Istituzionale Open Access dell'Università di Torino

**System and method for modifyng the location at which biliopancreatic secretions interact with the castrointestinal tract**

**This is the author's manuscript**

*Original Citation:*

*Availability:*

This version is available <http://hdl.handle.net/2318/130729> since

*Terms of use:*

Open Access

Anyone can freely access the full text of works made available as "Open Access". Works made available under a Creative Commons license can be used according to the terms and conditions of said license. Use of all other works requires consent of the right holder (author or publisher) if not exempted from copyright protection by the applicable law.

(Article begins on next page)



(51) International Patent Classification:  
*A61B 17/11* (2006.01) *A61F 5/00* (2006.01)

(21) International Application Number:  
PCT/EP2010/060285

(22) International Filing Date:  
16 July 2010 (16.07.2010)

(25) Filing Language: English

(26) Publication Language: English

(71) Applicant (for all designated States except US):  
**ETHICON ENDO-SURGERY, INC.** [US/US]; 4545  
Creek Road, Cincinnati, OH 45242-2839 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **ALBRECHT, Thomas Edward** [US/US]; 9543 Raven Lane, Cincinnati, OH 45242 (US). **STOKES, Michael, J.** [US/US]; 8 Sleepy Hollow Ln, Cincinnati, OH 45244 (US). **PAS-TORELLI, Alessandro** [IT/IT]; Via Francesco Sivori, 5, I-00136 Roma (IT). **ORTIZ, Mark Steven** [US/US]; 1145 Glen Echo Ln, Milford, OH 45150 (US). **LADD, Douglas Ned** [US/US]; 6950 Turpin View Drive, Cincin-

nati, OH 45244 (US). **AREZZO, Alberto** [IT/IT]; Via San Fermo, 3, I-10133 Torino (IT).

(74) Agents: **LEIHKAUF, Steffen Falk** et al.; c/o Jacobacci & Partners S.p.A., Via Senato, 8, I-20121 Milano (IT).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK,

[Continued on next page]

(54) Title: SYSTEM AND METHOD FOR MODIFYING THE LOCATION AT WHICH BILIOPANCREATIC SECRETIONS INTERACT WITH THE GASTROINTESTINAL TRACT

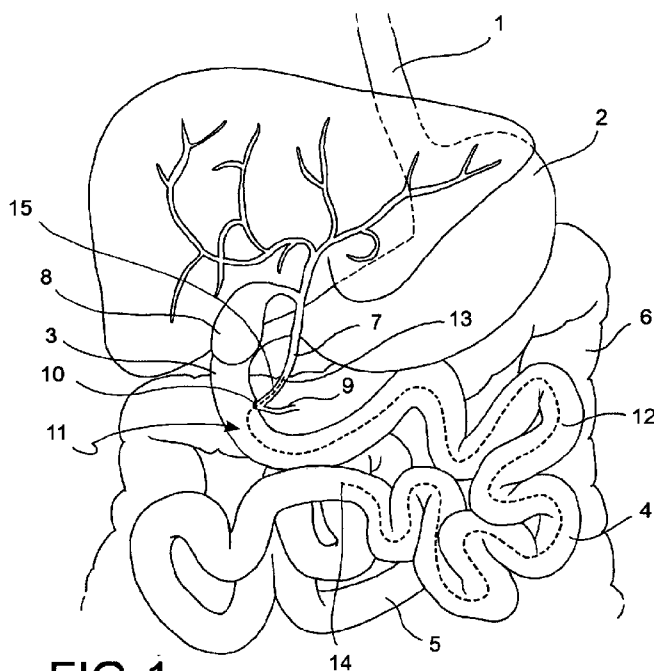


FIG. 1

(57) Abstract: A system (11) for diverting biliopancreatic secretions comprises a bile diversion conduit (12) having a proximal open end (13) adapted to be connected in fluid communication with the bile duct (7) to collect biliopancreatic secretions and a distal open end (14) adapted to discharge the biliopancreatic secretions to a location downstream in the gastrointestinal tract (3, 4, 5) and securing means (16) configured to anchor a proximal end portion (15) of the bile diversion conduit (12) to a lumen wall near the ampulla of Vater (10), such that the conduit proximal open end (13) remains inserted through the ampulla of Vater (10) in the bile duct (7).



---

SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, **Published:**  
GW, ML, MR, NE, SN, TD, TG).

— *with international search report (Art. 21(3))*

**"SYSTEM AND METHOD FOR MODIFYING THE LOCATION AT WHICH  
BILIOPANCREATIC SECRETIONS INTERACT WITH THE GASTROINTESTINAL TRACT"**

**DESCRIPTION**

The present invention relates, in general, to devices and methods for surgically influencing  
5 the digestion of a patient with the aim to treat metabolic disorders, such as morbid obesity  
and related co-morbidities, such as diabetes, heart disease, stroke, pulmonary disease, and  
accidents.

Numerous non-operative therapies for morbid obesity have been tried in the past with  
virtually no permanent success.

10 Surgical methods of treating morbid obesity, such as open, laparoscopic and endoluminal  
gastric bypass surgery aiming to permanent malabsorption of the food, have been  
increasingly used with greater success. However, current methods for performing a gastric  
bypass involve time-consuming and highly dexterity dependent surgical techniques as well  
as significant and generally highly invasive modifications of the patient's gastrointestinal  
15 anatomy. These procedures are reserved only for the severely obese patients because they  
have a number of significant complications, including the risk of death. In order to avoid the  
drawbacks of gastric bypass surgery and to influence the digestion of a patient in a more  
specific and aimed way, the present invention focuses on methods and devices for primarily  
influencing and modifying the entero-hepatic bile cycling rather than the digestive tract. To  
20 this end, the following possible approaches and mechanisms of action on the entero-hepatic  
bile cycling are contemplated:

- modification of the entero-hepatic bile cycling frequency, particularly bile cycle acceleration;
- modification of the physiological signaling triggered by the contact and interaction of the bile  
with the food in the intestine and by the contact of the bile with the intestinal wall;
- 25 - modification of the food absorbability by modifying the contact space and time between the  
bile and the food or chime in the intestine as well as by an aimed separation of the bile from  
the food.

A known minimally invasive bypass system and method for modifying the location at which  
bile and pancreatic secretions interact with nutrients in a gastrointestinal tract has been  
30 discussed in US 2005085787 A1. The known system comprises a conduit having a first end  
which diverts bile and pancreatic secretions from the ampulla of Vater to a location  
downstream in the gastrointestinal tract and a second end attached to the ampulla of Vater  
through sutures, staples, or hooks or by means of a cap forming a cavity with a plurality of  
channels to capture the tissue around the ampulla of Vater and at least one wire to pierce

through the tissue trapped in the cap and secure it thereto. While suturing or stapling the very delicate tissue of the ampulla of Vater is undesirably because of the risk of lesions and subsequent infections and pancreatitis, the proposed is structurally complex and requires a very accurate positioning and vacuum suction to pull the ampulla of Vater into the tissue receiving cavity of the cap, without squeezing or obstructing its opening. Moreover, the implanted cap favors the harboring of bacteria and subsequent infections and pancreatitis.

A general aim of the present invention is therefore to provide alternative minimally invasive systems and methods for modifying the location at which biliopancreatic secretions interact with nutrients in a gastrointestinal tract, which obviates at least some of the problems and drawbacks discussed in connection with the prior art.

A further specific aim of the present invention is to provide a system and method for modifying the location at which biliopancreatic secretions interact with nutrients in a gastrointestinal tract, being structurally simpler and easier to deploy than the discussed prior art solutions.

These aims are achieved by a system for modifying the location at which biliopancreatic secretions interact with nutrients in a gastrointestinal tract, comprising:

- a flexible bile diversion conduit having a proximal open end adapted to be fluid connected to the common bile duct to collect bile and or pancreatic juices and a distal open end adapted to discharge the biliopancreatic secretions to a location downstream in the gastrointestinal tract,

- securing means (16) cooperating with a proximal end portion (15) of the bile diversion conduit (12) and configured to anchor to a lumen wall such that the conduit proximal open end (13) remains inserted through the ampulla of Vater (10) in the bile duct (7).

This allows to collect the biliopancreatic fluid directly in the biliary tree, reducing the risk of obstruction of the ampulla of Vater, and diverting the biliopancreatic fluid to a point further distal in the gastrointestinal tract.

By modifying the location at which enzymatic fluids interact with nutrients from food fluids in the GI tract, less nutrients from the food fluids will be absorbed by the body, the effectiveness of enzyme and emulsifying reagent reacting with the food fluids will be decreased, and more of the food fluids will be excreted resulting in a weight loss. Thus, the proportion of absorbed food fluids to excreted food fluids is changed which results in the weight loss. Additionally, the altered contact space and time between biliopancreatic juices and the intestinal wall will influence the physiological signaling mechanism and the bile cycling time of the patient which can have beneficial effects on the control of diabetes.

In accordance with an aspect of the invention, the securing means comprise an elastic clip having a peripheral frame delimiting a central opening adapted to receive the ampulla of Vater, a plurality of tissue anchoring teeth formed on the peripheral frame and protruding into the central opening to grip the tissue and at least one conduit connector formed on the peripheral frame and adapted to engage the bile diversion conduit.

In accordance with a further aspect of the invention, the securing means comprise an expandable section formed around the proximal end portion of the bile diversion conduit, the expandable section adapted to radially expand from an initial retracted configuration to an expanded configuration which prevents withdrawal of the proximal end portion of the conduit through the sphincter of ODDI.

In accordance with aspects of the invention, the expandable section may comprise preloaded elastic expanding elements, shape memory expanding elements, inflatable balloon portions, balloon expandable stents, wedge expandable portions, wedge expandable stents.

In accordance with a further aspect of the invention, the securing means comprises an RF conducting outer surface formed on the proximal end portion of the bile diversion conduit and an RF source connectable to the RF conducting surface and adapted to operate a controlled tissue damage on the bile duct adjacent the RF conducting outer surface to stick the bile duct to the proximal end portion of the bile diversion conduit.

In accordance with a further aspect of the invention, the securing means comprises a fixating agent dispenser adapted to dispense a fixating promoting agent, such as glue or acid, on the external surface of the proximal end portion of the bile diversion conduit to stick the bile duct thereto.

In accordance with a yet further aspect of the invention, the securing means comprises a plurality of anchoring barbs protruding from the proximal end portion of the bile diversion conduit and having tips facing in a distal direction so that they pierce the tissue of the bile duct or papilla of Vater when pulled distally by the peristaltic forces of the intestine.

In accordance with a yet further aspect of the invention, the securing means comprises an anchoring ring formed by or connectable to the proximal end portion of the bile diversion conduit and having a plurality of proximally protruding anchoring needles with barbs adapted to pierce the tissue around the papilla of Vater and to prevent withdrawal therefrom.

In accordance with an aspect of the invention, the securing means comprises a helical anchor which is connected with the proximal end portion of the bile diversion conduit and has a pointed tip adapted to pierce the bile duct or papilla of Vater from inside and the anchor is rotatable to screw into the tissue wall, thereby fixating the bile diversion conduit inside the

bile duct.

In accordance with a yet further aspect of the invention, the system comprises supplementary anchoring means adapted to anchor the bile diverting conduit in a location in the GI tract at a distance from the securing means. This creates a redundant fixation of the bile diverting conduit to better resist against peristalsis forces.

The aims of the present invention are also achieved by a method for modifying the location at which biliopancreatic secretions interact with nutrients in a gastrointestinal tract, comprising the steps of:

- introducing a flexible bile diversion conduit in the GI tract;
- inserting a proximal open end of the bile diversion conduit through the ampulla of Vater in the common bile duct to collect bile and or pancreatic juices;
- positioning a distal open end of the bile diversion conduit in a second location in the gastrointestinal tract distal of the ampulla of Vater to divert the biliopancreatic secretions to the second location,
- securing a proximal end portion of the bile diversion conduit to the lumen wall at the ampulla of Vater, such that the proximal open end of the bile diversion conduit is inserted through the ampulla of Vater in the common bile duct.

In accordance with an aspect of the invention, the method comprises the steps of:

- a) affixing an elastic clip to an endoscope;
- b) placing the endoscope transorally in the gastrointestinal tract to a position near the ampulla of Vater;
- c) visualizing the ampulla of Vater;
- d) attaching the elastic clip to the ampulla of Vater from inside the intestine;
- e) attaching the proximal end portion of the bile diversion conduit to the elastic clip.

The fixation of the bile diversion conduit through the application of an elastic clip initially affixed to the endoscope obviates the need of complicated fixating mechanisms and techniques and improves the visualization during the deployment of the clip and of the bile diverting conduit.

In accordance with a further aspect of the invention, the method comprises the steps of:

- transporting an endoscopic grasper through an instrument channel of the endoscope to the ampulla of Vater;
- before attaching the clip to the ampulla of Vater, grasping the ampulla of Vater by means of the endoscopic grasper and pulling it through a central opening of the clip.

These and other aspects and advantages of the present invention shall be made apparent from the accompanying drawings and the description thereof, which illustrate embodiments of the invention and, together with the general description of the invention given above, and the detailed description of the embodiments given below, serve to explain the principles of the present invention.

- Figure 1 illustrates a method and system for modifying the location at which biliopancreatic secretions interact with nutrients in a gastrointestinal tract in accordance with an embodiment of the invention;

- Figure 2 illustrates a detail of the system in figure 1 in accordance with an embodiment;

- Figures 2A to 2D illustrate means and method steps for fixating a proximal end portion of a bile diverting conduit in the ampulla of Vater in accordance with an embodiment;

- Figure 2E illustrates an exemplary embodiment of an elastic clip for fixating a proximal end portion of a bile diverting conduit to the ampulla of Vater;

- Figures 3A and 3B illustrate means and method steps for fixating a proximal end portion of a bile diverting conduit in the ampulla of Vater in accordance with an embodiment;

- Figure 3C illustrates a further exemplary embodiment of a means for fixating a proximal end portion of a bile diverting conduit in the ampulla of Vater;

- Figure 4 illustrates means and a method for fixating a proximal end portion of a bile diverting conduit in the ampulla of Vater in accordance with a further embodiment of the invention;

- Figure 5 illustrates means and a method for fixating a proximal end portion of a bile diverting conduit in the ampulla of Vater in accordance with a yet further embodiment of the invention;

- Figure 5A illustrates a further exemplary embodiment of a means for fixating a proximal end portion of a bile diverting conduit in the ampulla of Vater;

- Figure 6 illustrates means and a method for fixating a proximal end portion of a bile diverting conduit in the ampulla of Vater in accordance with a further embodiment of the invention;

- Figure 7A is a cross-sectional view of a device for fixating a proximal end portion of a bile diverting conduit in the ampulla of Vater in accordance with a further embodiment of the invention;

- Figures 7B and 7C illustrate method steps for fixating a proximal end portion of a bile diverting conduit in the ampulla of Vater using the device in figure 7A;

- Figures 8 to 14 illustrate supplementary anchoring devices and methods for anchoring the



system in the GI tract in accordance with embodiments of the invention;

- Figure 15A is a longitudinal cross-sectional view of a device for fixating a proximal end portion of a bile diverting conduit in the ampulla of Vater in accordance with a further embodiment of the invention;

5 - Figure 15B is a frontal view of the device in figure 15A;

- Figure 15C illustrates a detail of an activating tool for the device in figure 15A;

Referring to the drawings where like numerals denote like anatomical structures and components throughout the several views, figure 1 is a partial view of the abdominal cavity of a patient, depicting the gastrointestinal tract with the esophagus 1, stomach 2, duodenum 3, jejunum 4, ileum 5, colon 6, as well as the hepatic-biliary system with the liver, the biliary tree 7 with gall bladder 8, the pancreatic duct 9 and the mayor duodenal papilla of Vater 10 through which the bile and pancreatic fluid normally enter the duodenum 3. Figure 1 shows further a system 11 for modifying the location at which biliopancreatic secretions interact with nutrients and with the intestinal wall in a gastrointestinal tract.

15 The system 11 comprises a bile diversion conduit 12, particularly a catheter, having a proximal open end 13 adapted and intended to be connected in fluid communication with the common bile duct 7 to collect bile and or pancreatic juices and a distal open end 14 adapted to discharge the biliopancreatic secretions to a location significantly further downstream in the gastrointestinal tract 3, 4, 5. The system 11 comprises further securing means 16  
20 connected or connectable to a proximal end portion 15 of the bile diversion conduit 12 and having a tissue anchoring section adapted to anchor to the lumen wall at the ampulla of Vater 10, such that the conduit proximal open end 13 is and remains inserted through the ampulla of Vater 10 in the common bile duct 7. If not otherwise specified, in the present description, the expressions "common bile duct", "biliary tree" and "bile duct" define the  
25 natural lumen or lumens which transport bile and pancreatic juices to the duodenum and which are considered to terminate distally inside the ampulla of Vater.

The bile diverting conduit 12 may be a flexible tube large enough in diameter such that the enzymes may pass through the flexible tube without forming stones or becoming infected. In an alternative embodiment, the bile diverting conduit 12 may contain a plurality of apertures  
30 to allow some enzymatic fluids to pass through to prevent injury or death to the patient should the conduit become clogged. The bile diverting conduit 12 may also have a side port (not shown) to allow fluids, such as saline, or gas to pass through the conduit to extend, straighten, or unfurl the conduit into the GI tract. This may also ensure that the lumen of the bile diverting conduit 12 remains free and clear of any obstructions. However, the bile

diverting conduit 12 may unfurl itself by having the bile and pancreatic secretions fill the conduit or through intestinal peristalsis.

The length of the bile diversion conduit 12 is selected depending on the anatomical conditions of the patient and the amount of weight the patient would like to lose. Since the amount of malabsorption resulting from placement of the conduit 12 is related to the length of the bowel by-passed by the conduit, adjustments in the length of the bile diversion conduit 12 would be beneficial and are contemplated by the present invention. Thus, the location of where the enzymatic fluids are to exit in the GI tract may be variable and may be determined by the doctor. The bile diversion conduit 12 may be shortened by trimming its length prior to insertion into a patient's body. Additionally, a filamentous member may be attached to the conduit such that when the filamentous member is pulled, the conduit 12 will shorten in an accordion style. The ability to adjust the length of the bile diversion conduit 12 allows for the adjustment of the weight loss effects and control of diabetes.

In accordance with an embodiment, the conduit proximal end portion 15 may be bifurcated or Y-shaped and defines a proximal open bile end 13 intended and adapted to be inserted in the bile duct 7 proximal to the junction point with the pancreatic duct 9, and a proximal open pancreatic end 13' intended and adapted to be inserted in the pancreatic duct 7.

The conduit 12 may be made of any material that may be absorbable by the body such as polyglycolated resins, polygalactic acid materials, and other similar materials or non-absorbable materials such as silicone, polyethylene, polypropylene, butylated rubber, latex, and the like. If the conduit 12 is made of non-absorbable material, it may be easily removed from the patient when a target or ideal weight is obtained. The device may also be easily removed with an endoscope through the patient's mouth. Alternatively, the securing means used to fixate the conduit 12, may be made of an absorbable material to allow the conduit 12 to pass through the anal canal. In another embodiment, the conduit 12 may be made of a semi-permeable material, such as Goretex®, to selectively allow certain bodily fluids to pass through the conduit. For instance, the semi-permeable material may allow water to enter the conduit to assist in the flow of biliopancreatic secretions through the conduit 12.

In accordance with an embodiment (figures 2A to 2M), the securing means 16 comprise an elastic clip 17 having an elastically deformable peripheral frame 18 delimiting a central opening 22 adapted to receive the ampulla of Vater 10, as well as a plurality of tissue anchoring teeth 19 formed on the peripheral frame 18 and protruding inside the central opening 22 to grip the tissue of or around the ampulla of Vater. The clip 17 can be elastically bent, e.g. about a bending axis 23 indicated with a dash-dotted line in figures 2E and 2K, and

inserted over a clip receiving portion of a clip applier 24, e.g. an endoscope, so that the anchoring teeth 19 are facing proximally, i.e. towards the tissue to which the clip 17 shall be applied. The clip applier 24 may comprise a pushing portion 25 adapted to push the clip 17 proximally out of engagement with the receiving portion, so that the clip 17 recovers its initial shape and the anchoring teeth move inward and clamp and or pierce the tissue of the ampulla of Vater.

The clip 17 comprises further at least one conduit connector for a connection between the clip 17 and the bile diversion conduit 12.

In an exemplary embodiment, the conduit connector comprises a hole 20 for the connection with the proximal end portion 15 of the bile diversion conduit 12. To this end the bile diversion conduit 12 may be inserted in the hole 20 before or after deploying the clip 17 and the conduit proximal end portion 15 may have an outwardly protruding collar or shoulder 26 which engages the edge of hole 20 to prevent the bile diverting conduit 12 from being pulled distally out of the hole 20.

In accordance with an embodiment, the hole 20 may be formed in a beam 27 extending diametrically between two opposite portions of the peripheral frame 18 of clip 17 and the clip applier 24 may have a longitudinal slot 28 for receiving the beam 27 when the clip 17 is attached to it during endoluminal transport and deployment (Figs. 2L and 2M).

When the bile diverting conduit 12 is inserted in the hole 20 of the clip 17 before deployment of the latter, the conduit 12 may be inserted with its distal end 14 distally until the shoulder 26 of the conduit proximal end portion 15 abuts against the rim of the hole 20. In this case, the proximal end 13 of conduit 12 may be inserted in the papilla of Vater using e.g. an ERCP (Endoscopic Retrograde Cholangio Pancreatography) like technique before applying the clip 17 to the ampulla of Vater.

The ERCP procedure involves passing a flexible endoscope through the mouth, esophagus, and stomach into the duodenum near the papilla of Vater 10. The doctor then passes the bile diversion conduit 12 through a channel in the endoscope and out into view in the duodenum and inserts it into the papilla of Vater.

Alternatively, when the bile diverting conduit 12 is inserted in the hole 20 of the clip 17 after deployment of the latter, the conduit 12 may be inserted with its proximal end 13 proximally until the (resiliently configured) shoulder 26 of the conduit proximal end portion 15 is pushed through the hole 20 and snap engages the rim thereof. In this case, the introduction of the conduit proximal end 13 in the papilla of Vater may be operated contemporaneously with the fixation in the hole 20, for example by an endoscopic ERCP technique.

In accordance with a further embodiment (Figs. 2E to 2H), the conduit connector comprises two opposite clamping jaws 21 formed on the peripheral frame 18 of the clip and projecting inside the central opening 22 so that they can engage (e.g. with shape coupling or interference fit) the conduit proximal end portion 14 to retain it in the desired position.

- 5 The clip 17 may be configured such that, when the clip 17 is bent and inserted over the receiving portion of clip applier 24, the clamping jaws 21 are received in the longitudinal slot 28 (Figures 2G and 2H) or, alternatively, the clamping jaws 21 are seated against an external surface of the applier 24 (Figure 2F) and snaps back to its programmed position (Figure 2E) upon deployment of the clip 17. The clamping jaws 21 may be oriented slightly proximally so  
10 that the bile diverting conduit 12 can be pushed proximally between them and distal pulling of the bile diverting conduit 12 will increase the clamping force acting on the conduit 12.

Generally spoken, the above described method for fixating the bile diversion conduit in the gastrointestinal tract comprises the steps of:

- a) affixing the elastic clip to an endoscope;
- 15 b) placing the endoscope transorally in the gastrointestinal tract to a position near the ampulla of Vater;
- c) visualizing the ampulla of Vater;
- d) attaching the elastic clip to the ampulla of Vater  
from inside the intestine;
- 20 e) attaching the proximal end portion of the bile diversion conduit to the elastic clip.

In accordance with an embodiment, an endoscopic grasper 61 may be transported through an instrument channel of the endoscope 24 to the ampulla of Vater 10 and, before attaching the clip 17 to the ampulla of Vater, the ampulla of Vater may be grasped with the endoscopic grasper 61 and pulled at least partially through the central opening 22 of the clip 17 to assure  
25 that the clip 17 grips a sufficient amount of tissue for a reliable connection.

In accordance with a further embodiment (Figures 3A to 3C), an expandable section 29 is formed on the outside of the proximal end portion 15 of the bile diversion conduit 12. The expandable section 29 is adapted to radially expand from a retracted configuration which allows endoluminal transportation of the conduit 12 and introduction of its proximal open end  
30 13 in the bile duct (Figure 3A) to an expanded configuration (Figure 3B) which prevents withdrawal of the proximal end portion 15 of the conduit 12 through the sphincter of ODDI.

In accordance with an exemplary embodiment, the expandable section 29 may comprise shape memory expanding elements or elastically preloaded expanding elements 30 formed or connected at the proximal conduit end portion 15 in a section which is intended to be

arranged proximal to the sphincter of ODDI.

Releasable retaining means, such as releasable retaining hooks 31 adapted to tension and lock the expanding elements 30 in a flattened shape (Figure 3A) or a strippable retaining sleeve 32 (Figure 3C) adapted to cover and radially compress the expanding elements 30, may be provided for holding the expandable section 29 in the retracted configuration during endoluminal transportation of the bile diversion conduit 12 and introduction in the bile duct, as well as for a controlled expansion of section 29 during deployment.

Also in this case, the bile diversion conduit 12 can be transported and introduced in the papilla of Vater using the ERCP (Endoscopic Retrograde Cholangio Pancreatography) like technique and, after positioning of the expandable section 29 in the bile duct proximal to the sphincter of ODDI, the expandable section 29 is expanded by releasing the retaining means so that the conduit end portion 15 remains anchored in the bile duct 7.

In accordance with further embodiments and variants, the expandable section 29 may comprise a possibly cone shaped or wedge shaped inflatable chamber 33 (Figure 6) or a balloon expandable stent or a wedge expandable stent or a stent which is expandable by torsional deformation.

Figure 4 illustrates an embodiment, in which the securing means 16 comprises an RF conducting outer surface section 34, such as a metallic external liner or a metallic winding or mesh, formed on the proximal end portion 15 of the bile diversion conduit 12 and an RF source connectable to the RF conducting surface section 34 and adapted to operate a controlled damage on the bile duct 7 adjacent the RF conducting surface section 34 to stick the bile duct 7 to the conduit proximal end portion 15.

The RF source may be a RF generator with power and temperature control, such as a closed-loop temperature control cooperating with embedded thermocouples in the RF conducting section 34.

For example, the Atakr® II RF Generator by Medtronic, Inc, Minneapolis, MN, USA or the Stockert 70 RF Generator by Biosense Webster Biosense Webster, Inc, 3333 Diamond Canyon Road, Diamond Bar, CA 91765, USA, may be used as RF generator.

The bile diverting conduit 12 catheter is transported in the GI tract and introduced through the papilla of Vater into the bile duct 7 by means of the above described endoscopic ERCP like technique and, while the distal catheter portion is still inside the instrument channel of the endoscope, the RF conducting surface section 34 is electrically connected with the extracorporeal RF source and energized by the latter such that the RF pulsed current and heat creates a controlled and localized tissue damage at the bile duct lumen wall sufficient to

stick the tissue to the conduit proximal end portion 15 and thereby anchoring the conduit 12 in the desired position. After the RF treatment and anchoring of the conduit proximal end portion 15, the distal open end 14 of the conduit 12 is positioned in the point of planned bile diversion further distally in the GI tract, e.g. in a distal tract of the duodenum 3, in the jejunum 4 or in the ileum 5.

Also in this case the conduit proximal end portion 15 may be Y-shaped to enter both the bile duct 7 proximal to the junction with the pancreatic duct 9 and the pancreatic duct 9. The RF conducting external surface section 34 may be provided in both branches of the Y- end portion or in a common section of the end portion 15 distal to the bifurcation point.

In accordance with an embodiment, the controlled damage of the bile duct 7 may be operated by a distinct RF ablation catheter, such as for example the ThermoCool® Irrigated Tip RF Ablation Catheter by Biosense Webster, Inc, 3333 Diamond Canyon Road, Diamond Bar, CA 91765, USA.

The distinct RF ablation catheter is positioned through an instrument channel of an endoscope by the above described ERCP like technique, connected to an RF generator and energized to operate the controlled and localized tissue damage in the bile duct. Then, the distinct RF ablation catheter is removed through the instrument channel of the endoscope and the bile diversion conduit 12 catheter is inserted in the instrument channel of the endoscope and its proximal end portion 15 is introduced through the papilla of Vater in the bile duct and in contact with the damaged lumen wall portion, so that they can stick to each other.

In accordance with a further embodiment, a fixating agent dispenser may be provided and possibly embedded in the conduit proximal end portion 15, which is adapted to dispense a fixating promoting agent, such as glue or acid, on the external surface of the proximal end portion 15 of the bile diversion conduit 12 to stick it to the bile duct 7.

Figures 5 and 5A illustrate an embodiment in which a plurality of anchoring barbs 35 protrude from the proximal end portion 15 of the bile diversion conduit 12 and have tips facing in a distal direction so that they pierce the tissue of the bile duct 7 or papilla of Vater 10 when pulled distally by the peristaltic forces of the intestine. During deployment of the conduit 12 using the previously described ERCP like endoscopic approach, the barbs 35 may be covered by a strippable protecting sleeve 36 which is inserted over at least a part of the proximal end portion 15 during transport and positioning of the conduit 12 catheter and, subsequently, distally stripped away to expose the barbs 35.

Figures 7A to 7C illustrate a method and system in accordance with an embodiment, in

which an anchoring ring 37 formed on the outside of the conduit proximal end portion 15 or connectable to the latter. The anchoring ring 37 comprises a plurality of circumferentially distributed proximally protruding anchoring needles 38 with barbs adapted to pierce the tissue around the papilla of Vater 10 and to prevent withdrawal of the ring 37 therefrom. A protective ring 39 may be provided to cover the anchoring ring 37 during endoluminal transport through the GI tract and positioning over the ampulla of Vater. The anchoring ring 37 can be received by a ring applier head of an endoscope 39 and the protective ring 39 may be connected to the ring applier head and shiftable in a distal direction against an elastic preload, so that it exposes the anchoring needles 38 of the anchoring ring 37 when pushed proximally against the lumen wall around the papilla of Vater.

In an alternative embodiment, the protective ring 39 may be coupled with the anchoring ring 37 in an axially movable manner and elastically preloaded in a proximal direction or otherwise held in a proximal position in which the protective ring 39 covers the anchoring needles 38. When the ring assembly 37, 39 is pushed proximally against the lumen wall around the papilla of Vater, the protective ring 39 is moved distally away, thereby exposing the anchoring needles 38 of the anchoring ring 37. After deployment of the anchoring ring 37, the protective ring 39 may fall off from the latter or remain attached to it.

The conduit proximal end portion 15 is extend through an internal opening of the anchoring ring 37 and may be affixed to or integrally formed with the anchoring ring 37 before endoluminal placement thereof or inserted through and connected to the anchoring ring 37 after its deployment. Endoluminal transport and deployment of the bile diversion conduit 12 may be operated transorally using the previously described endoscopic ERCP like technique. Figures 15A to 15E illustrate an embodiment, in which

a helical (or corkscrew shaped) anchor 41 is connected with the proximal end portion 15 of the bile diversion conduit 12. The helical anchor 41 has a pointed tip adapted to pierce the bile duct 7 or papilla of Vater from inside and the anchor is rotatable to screw into the tissue wall, thereby fixating the bile diversion conduit 12 inside the bile duct 7.

In accordance with an embodiment, the conduit proximal end portion 15 may define a cylindrical internal anchor seat 42 adapted to receive the anchor 41 and a lateral hole through which the anchor tip can be pushed outside the conduit end portion 15 into the adjacent tissue through which the anchor 41 can be screwed out of the anchor seat 42 and into the lumen. The anchor 42 may further form a tool portion 43 adapted to be engaged by a rotating tool 44, e.g. a torsionally stiff but flexible rotation transmitting cable or chain with a slotted end portion 45 or grasping portion.

The tool 44 may be inserted in the conduit catheter 12 and coupled with the tool portion 43 of the anchor 41 before insertion of the conduit 12 in the patient's body. After preparation of the conduit 12 and tool 44, the conduit 12 catheter can be inserted transorally in the GI tract and introduced in the bile duct 7 using the above described ERCP technique and, after the  
5 conduit proximal end portion 15 has been correctly positioned in the bile duct 7, the tool 44 is rotated to install the anchor 44 in the lumen wall.

In accordance with an embodiment (Figure 15 D) the system is configured so that the helical anchor 41 is screwed in a proximal direction with respect to the anchor seat 42. In an alternative embodiment (Figure 15E), the helical anchor 41 is screwed in a distal direction  
10 with respect to the anchor seat 42.

In both embodiments, the conduit proximal end portion 15 may optionally form an enlarged section 46 proximal to the position of the anchor 41 in which the enlarged section 46 has an outer diameter greater than the inner diameter of the deployed anchor 41, thereby creating an additional shape coupling between the conduit 12 and the lumen portion containing the  
15 anchor 41.

The present invention further contemplates the possibility of placing the bile diversion conduit 12 in the intestine and introducing the conduit proximal end 15 in the papilla of Vater 10 by laparoscopically accessing the abdominal space, translumenally accessing the duodenum near the papilla of Vater and placing the conduit 12 through the duodenum in the desired  
20 position within the intestine and, from inside the duodenum, laparoscopically introducing the conduit proximal end 15 into the papilla of Vater.

In accordance with a further embodiment, the system 11 comprises supplementary anchoring means adapted to anchor the bile diverting conduit 12 in a location in the GI tract at a distance from the securing means 16 and proximal to the ampulla of Vater. This creates  
25 a redundant fixation of the bile diverting conduit 12 to better resist against peristalsis forces.

Figure 8 shows an embodiment, in which the bile diversion conduit 11 can be anchored to the intestinal wall by means of a submucosal band 47 inserted in the lumen wall and extending all around it such as to form an anchoring ring which creates a bottleneck portion in the intestinal wall, adapted to engage a corresponding annular anchoring groove 48  
30 formed in an annular anchoring portion 49 adapted to allow the intestinal contents to pass through and to which the conduit 12 may be connected by means of an anchoring wire 50.

Figure 9 illustrates a yet further exemplary embodiment, in which the conduit 12 can be anchored in the GI tract by means of a gastric stent 51 and an attached elastically expandable (possibly shape memory) arch 52 adapted to create a shape connection with the



stomach 2.

Figure 10 illustrates a yet further exemplary embodiment, in which the conduit 12 can be anchored in the GI tract by means of one or more T-tags 53 fired from the inside of the intestine in the intestinal wall, thereby forming fixation points, and connected with the bile diversion conduit 12 by a pull resistant anchoring wire 50.

Figures 11 and 11A illustrate a yet further exemplary embodiment, in which the conduit 12 can be anchored in the GI tract by means of an annular anchoring portion 54 having a plurality of anchoring barbs 55, said barbs 55 being movable, e.g. rotatable, from a rest position in which the barbs 55 are contained within the encumbrance of the anchoring portion 54 to enable unobstructed endoluminal transport of the anchoring portion 54, to a working position in which the barbs 55 protrude radially outward, thereby piercing the lumen wall and, hence, anchoring the anchoring portion 54 thereto. Also in this embodiment, the conduit 12 is connected to the anchoring portion 54 by a pull resistant anchoring wire 50.

In a further exemplary embodiment, illustrated in figures 12A, 12B, the conduit 12 can be anchored in the GI tract by means of a tubular or annular anchoring portion 56 having one or more anchoring holes 57 intended to face adjacent intestinal wall portions and adapted to allow these intestinal wall portions to be pulled into the holes 57 and fixed thereto. An endoluminal suction device 58 may be provided for sucking the lumen wall portions from inside the tubular anchoring portion 56 and pulling them in the anchoring holes 57, as well as means and methods for creating a permanent (mushroom head type) swelling of the lumen wall portion, preventing it from withdrawal from the anchoring holes 57. Such means and methods for creating a permanent swelling of the lumen wall portion may comprise the submucosal injection of a swelling agent or sclerosant agent or insertion of a plastic bead, e.g. Poly(methyl methacrylate) PMMA, in the tissue portions which have been previously pulled through the anchoring holes 57. The bile diversion conduit 12 is connected or connectable to the anchoring portion 56, e.g. by a pull resistant anchoring wire 50.

The yet described supplementary anchoring means can be endoluminally, particularly transorally inserted in the GI tract and affixed thereto. Alternatively, the supplementary anchoring means are positioned and fixated laparoscopically by creating a laparoscopic access port in the abdominal wall and accessing the duodenum transluminally through a cut performed in the duodenal wall.

The same laparoscopic approach and access port may be used for introducing and positioning the bile diversion conduit 12 in the intestine and for connecting its proximal end 13 in the bile duct 7, as well as for connecting the bile diversion conduit 12 with the

supplementary anchoring means.

Figure 13 shows a gastric coil 59 which can elastically deform from an extended configuration adapted for transoral or transnasal transportation thereof into the stomach 2, to an arched or circular configuration adapted to shape connect with the stomach 2 such as to provide an anchor for a pull resistant anchoring wire 50 which is connected to conduit 12.

In a further exemplary embodiment, illustrated in figure 14, the anchoring wire 50 can be connected, e.g. by means of T-tags, to a previously created plication 60 in the stomach wall.

The system and methods of the described invention can achieve a modification of the location at which enzymatic fluids interact with the intestinal wall and with nutrients from food fluids in the GI tract. As a consequence, less nutrients from the food fluids will be absorbed by the body, the effectiveness of enzyme and emulsifying reagent reacting with the food fluids will be decreased, and more of the food fluids will be excreted resulting in a weight loss. Moreover, the altered contact space and time between the biliopancreatic juices and the intestinal wall acts on the physiological signaling mechanism of the patient, thereby influencing diabetes and other co-morbidities of obesity.

On the basis of the preceding disclosure, those skilled in the art will appreciate the advantageous effects of the proposed connection systems and methods for fixating a bile diversion conduit in the ampulla of Vater, which are minimally invasive, structurally and functionally simple and robust and depend less from the surgical skills of the doctor.

Although preferred embodiments of the invention have been described in detail, it is not the intention of the applicant to limit the scope of the claims to such particular embodiments, but to cover all modifications and alternative constructions falling within the scope of the invention.

**CLAIMS**

1. A system (11) for modifying the location at which biliopancreatic secretions interact with nutrients and with the intestinal wall in a gastrointestinal tract, said system (11) comprising:

- a bile diversion conduit (12) having a proximal open end (13) adapted to be connected in fluid communication with the bile duct (7) to collect biliopancreatic secretions and a distal open end (14) adapted to discharge the biliopancreatic secretions to a location downstream in the gastrointestinal tract (3, 4, 5),

- securing means (16) configured to anchor a proximal end portion (15) of the bile diversion conduit (12) to a lumen wall near the ampulla of Vater (10), such that the conduit proximal open end (13) remains inserted through the ampulla of Vater (10) in the bile duct (7).

2. A system (11) according to claim 1, wherein the conduit proximal end portion (15) is bifurcated and defines a proximal open bile end (13) adapted to be inserted in the bile duct (7) proximal to the junction point with the pancreatic duct (9) and a proximal open pancreatic end (13') adapted to be inserted in the pancreatic duct (7).

3. A system (11) according to claim 1, wherein said securing means (16) comprise a clip (17) having:

- an elastically deformable peripheral frame (18) delimiting a central opening (22) adapted to receive the ampulla of Vater (10),

- tissue anchoring teeth (19) formed on the peripheral frame (18) and protruding inside the central opening (22),

- a conduit connector for a connection between the clip (17) and the bile diversion conduit (12).

4. A system (11) according to claim 3, comprising a clip applier (24) with a clip receiving portion and a pushing portion (25), in which said clip (17) is insertable over a clip receiving portion so that the anchoring teeth (19) are elastically bent proximally towards the tissue and the pushing portion (25) is adapted to push the clip (17) proximally out of engagement with the receiving portion, so that the clip (17) recovers its initial shape and the anchoring teeth (19) move inward, thereby clamping the tissue.

5. A system (11) according to claim 3 or 4, in which said clip (17) comprises a connecting hole (20) and the bile diversion conduit (12) is insertable in said hole (20), wherein the conduit proximal end portion (15) forms an outwardly protruding shoulder (26) adapted to engage a rim of hole (20) to prevent the bile diverting conduit (12) from being pulled distally out of the hole (20).

6. A system (11) according to claim 3 or 4, in which said clip (17) comprises two clamping

jaws (21) projecting from the peripheral frame (18) inward and adapted to engage the conduit proximal end portion (14) to retain it.

7. A system (11) according to claim 4, comprising a grasper (61) which can be inserted through an instrument channel of the clip applier (24) and adapted to grasp the ampulla of Vater and to pull it into the central opening (22) of the clip (17).

8. A system (11) according to claim 1 or 2, wherein said securing means (16) comprise an expandable section (29) formed on the outside of the conduit proximal end portion (15) in a position intended to be arranged in the bile duct proximal to the sphincter of ODDI, said expandable section (29) being radially expandable from a retracted configuration which allows endoluminal introduction of the expandable section (29) through the sphincter of ODDI, to an expanded configuration which prevents withdrawal of the expandable section (29) through the sphincter of ODDI.

9. A system (11) according to claim 8, in which the expandable section (29) comprises shape memory expanding elements.

10. A system (11) according to claim 8, in which the expandable section (29) comprises elastically preloaded expanding elements (30).

11. A system (11) according to any of claims 8 to 10, comprising releasable retaining means adapted to hold the expandable section (29) in the retracted configuration and to trigger expansion of expandable section (29).

12. A system (11) according to claim 8, wherein the expandable section (29) comprises a cone shaped inflatable chamber (33).

13. A system (11) according to claim 8, wherein the expandable section (29) comprises a balloon expandable stent.

14. A system (11) according to claim 8, wherein the expandable section (29) comprises or a wedge expandable stent.

15. A system (11) according to claim 8, wherein the expandable section (29) comprises a stent which is expandable by torque deformation.

16. A system (11) according to claim 1 or 2, wherein said securing means (16) comprise an RF conducting outer surface section (34) formed on the proximal end portion (15) of the bile diversion conduit (12) and connectable to an RF generator to operate a controlled damage on the bile duct (7), thereby sticking it to the conduit proximal end portion (15).

17. A system (11) according to claim 16, comprising an RF generator with power control and a closed-loop temperature control cooperating with an embedded thermocouple in the RF conducting section (34).

**18.** A system (11) according to claim 1 or 2, wherein said securing means (16) comprise a fixating agent dispenser arranged on the conduit proximal end portion (15), said dispenser being adapted to dispense a fixating promoting agent on the external surface of the conduit proximal end portion (15) for sticking it to the lumen wall.

5 **19.** A system (11) according to claim 1 or 2, wherein said securing means (16) comprise a plurality of anchoring barbs (35) protruding from the conduit proximal end portion (15) and having tips facing in a distal direction.

**20.** A system (11) according to claim 19, comprising a strippable protecting sleeve (36) covering the barbs (35).

10 **21.** A system (11) according to claim 1 or 2, in which said securing means (16) comprise an anchoring ring (37) comprising a plurality of circumferentially distributed proximally protruding anchoring needles (38) with barbs adapted to pierce the tissue around the papilla of Vater (10) and to prevent withdrawal of the anchoring ring (37) therefrom.

**22.** A system (11) according to claim 21, in which the conduit proximal end portion (15) extend through an internal opening of the anchoring ring (37) and is integrally formed with the anchoring ring (37).

in which

20 **23.** A system (11) according to claim 1 or 2, wherein said securing means (16) comprise a helical anchor (41) connected with the proximal end portion (15) of the bile diversion conduit (12), said anchor (41) being adapted to pierce the bile duct (7) from inside and to be rotated to screw into the tissue wall, thereby fixating the bile diversion conduit (12) inside the bile duct (7).

25 **24.** A system (11) according to any one of the preceding claims, comprising supplementary anchoring means adapted to anchor the bile diverting conduit (12) in a location in the GI tract proximal to the ampulla of Vater at a distance from the securing means (16).

**25.** A system (11) according to claim 24, wherein said supplementary anchoring means are selected in the group consisting of:

- a submucosal band (47) which can be inserted in the lumen wall to form an anchoring ring adapted to engage an annular anchoring groove (48) formed in an annular anchoring portion (49) to which the conduit (12) is connected by means of an anchoring wire (50),
- a gastric stent (51) and an attached expandable arch (52) adapted to create a shape connection with the stomach (2),
- T-tags (53) adapted to form fixation points in the GI lumen wall and connected with the bile diversion conduit (12) by a an anchoring wire (50),

- an annular anchoring portion (54) having a plurality of anchoring barbs (55), said barbs (55) being movable, from a rest position in which the barbs (55) are contained within the encumbrance of the anchoring portion (54) to a working position in which the barbs (55) protrude radially outward, thereby piercing the lumen wall, said bile diversion conduit (12) being connected to the anchoring portion (54) by a pull resistant anchoring wire (50),
  - an annular anchoring portion (56) having anchoring holes (57) adapted to face intestinal wall portions and to allow these intestinal wall portions to be pulled into the holes (57) and fixed thereto, and means for creating a permanent mushroom head type swelling of the wall portions, preventing it from withdrawal from the anchoring holes (57), said bile diversion conduit (12) being connected or connectable to the anchoring portion (56) by an anchoring wire (50),
  - a gastric coil (59) which can elastically deform from an extended configuration to an arched or circular configuration adapted to shape connect with the stomach (2) and an anchoring wire (50) connecting the bile diversion conduit (12) with the gastric coil (59),
  - T-tags adapted to create a gastric placcation and connected with the bile diversion conduit (12) by a an anchoring wire (50).
- 26.** A method for modifying the location at which biliopancreatic secretions interact with nutrients and with the intestinal wall in a gastrointestinal tract, said method comprising:
- introducing a flexible bile diversion conduit in the GI tract;
  - inserting a proximal open end of the bile diversion conduit through the ampulla of Vater in the common bile duct to collect bile and or pancreatic juices;
  - positioning a distal open end of the bile diversion conduit in a second location in the gastrointestinal tract distal of the ampulla of Vater to divert the biliopancreatic secretions to the second location,
  - securing a proximal end portion of the bile diversion conduit to the lumen wall near the ampulla of Vater, such that the proximal open end of the bile diversion conduit is inserted through the ampulla of Vater in the bile duct.
- 27.** Method according to claim 26, comprising the steps of:
- affixing an elastic clip to an endoscope;
  - placing the endoscope transorally in the gastrointestinal tract to a position near the ampulla of Vater;
  - visualizing the ampulla of Vater;
  - attaching the elastic clip to the ampulla of Vater from inside the intestine;

- attaching the proximal end portion of the bile diversion conduit to the elastic clip.

**28.** Method according to claim 27, comprising the steps of:

- transporting an endoscopic grasper through an instrument channel of the endoscope to the ampulla of Vater;

5 - before attaching the clip to the ampulla of Vater, grasping the ampulla of Vater by means of the endoscopic grasper and pulling it into a central opening of the clip.

**29.** Method according to claim 26, comprising the steps of:

10 - transporting the bile diverting conduit in the GI tract and introducing the conduit proximal end portion through the papilla of Vater into the bile duct by means of an endoscopic ERCP technique.

**30.** Method according to claim 26, comprising the steps of:

- operating a controlled damage of the bile duct wall by means of an RF ablation;

- sticking the damaged bile duct wall to the conduit proximal end portion.

15 **31.** Method according to claim 26, comprising the steps of:

- laparoscopically accessing the abdominal space and translumenally accessing the duodenum near the papilla of Vater;

- placing the bile diverting conduit laparoscopically through a cut in the duodenum wall in the desired position within the intestine and;

20 - from inside the duodenum, introducing the conduit proximal end (15) into the papilla of Vater.

**32.** Method according to claim 26, comprising the steps of:

- inserting supplementary anchoring means in the GI tract;

25 - fixating the supplementary anchoring means in a location in the GI tract proximal to the ampulla of Vater at a distance from the bile diverting conduit,

- connecting the bile diverting conduit to the supplementary anchoring means.

**33.** Method according to claim 31, wherein said supplementary anchoring means are transorally inserted in the GI tract and endoluminally affixed thereto.

30 **34.** Method according to claim 31, wherein said supplementary anchoring means are laparoscopically positioned and fixated in the GI tract by creating a laparoscopic access port in the abdominal wall and accessing the duodenum transluminally through a cut performed in the duodenal wall.

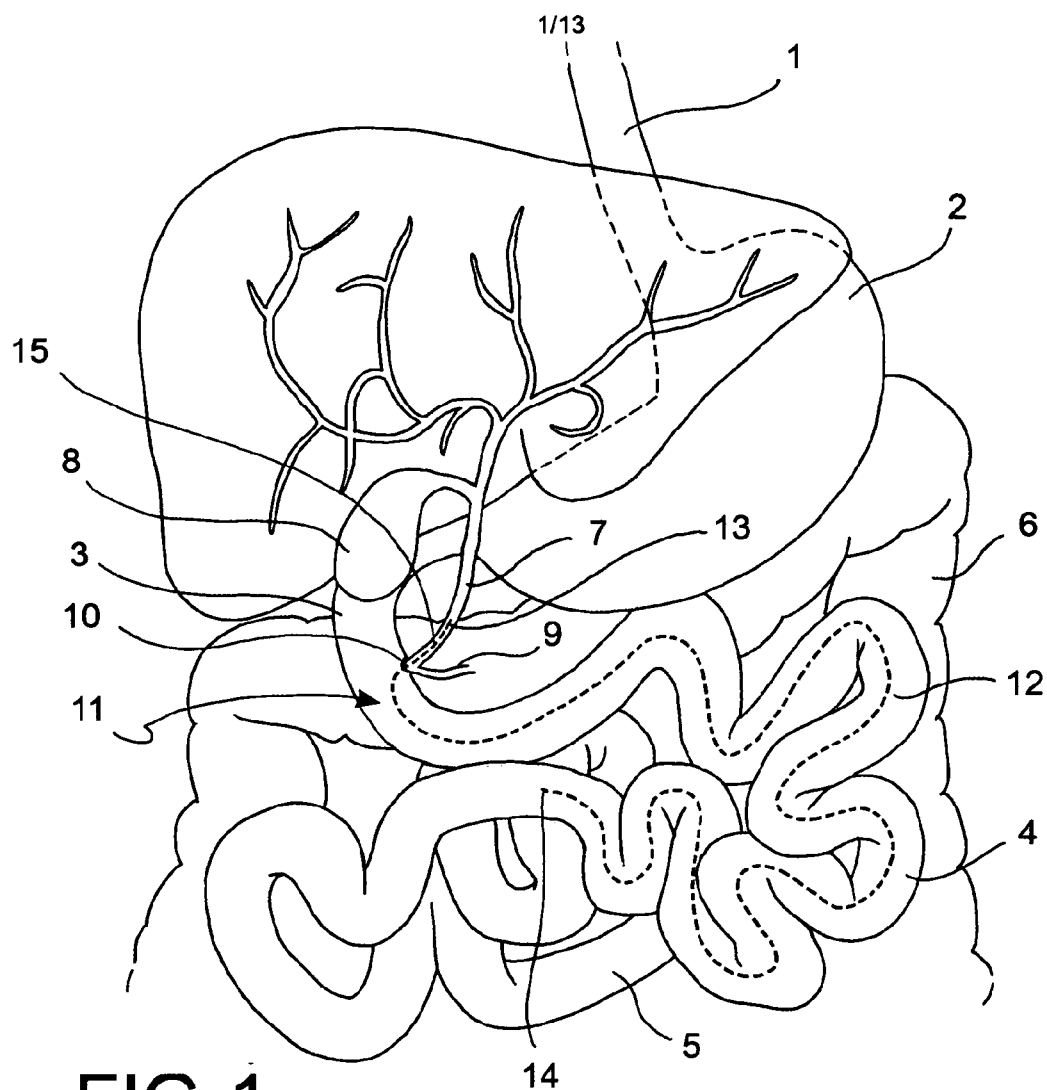


FIG. 1

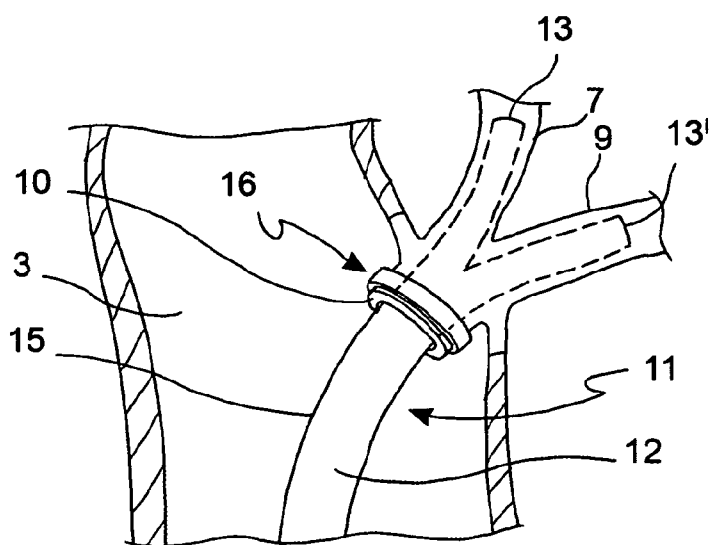


FIG. 2



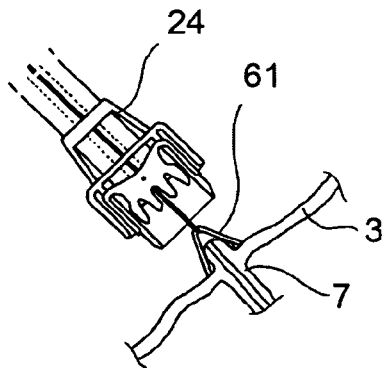


FIG. 2A

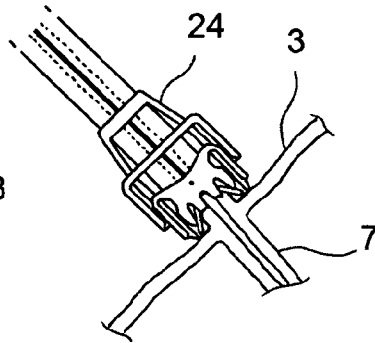


FIG. 2B

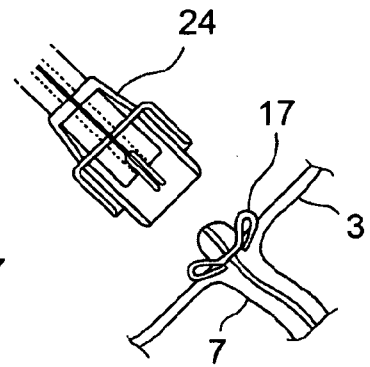


FIG. 2C

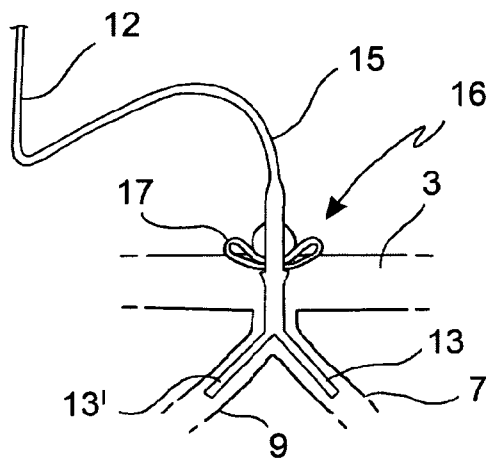


FIG. 2D

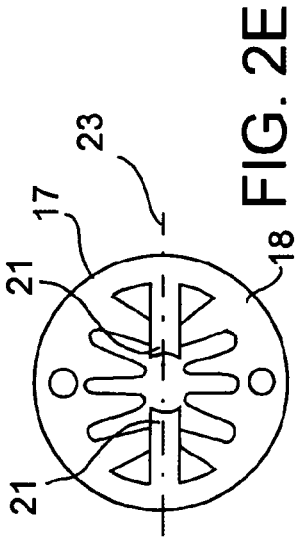


FIG. 2E

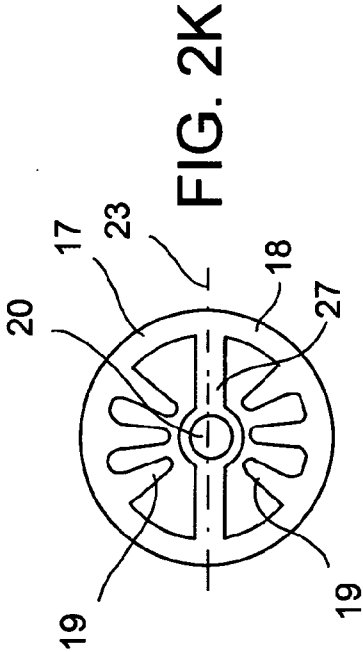


FIG. 2K

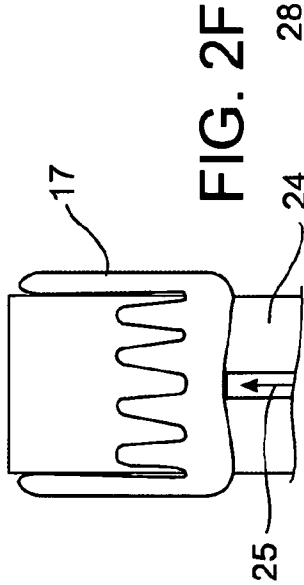


FIG. 2F

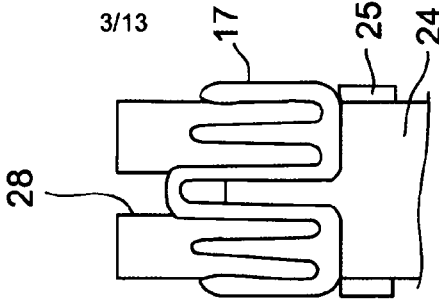


FIG. 2M

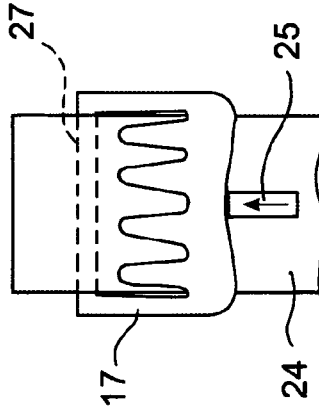


FIG. 2L

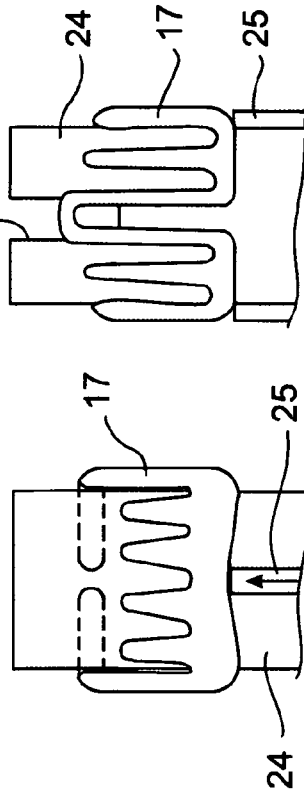


FIG. 2G

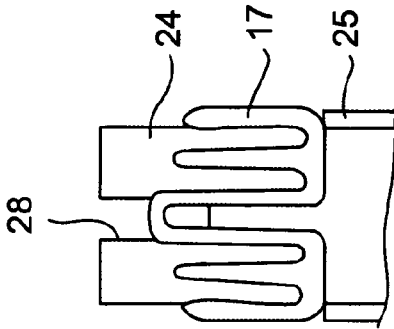


FIG. 2H

FIG. 3A

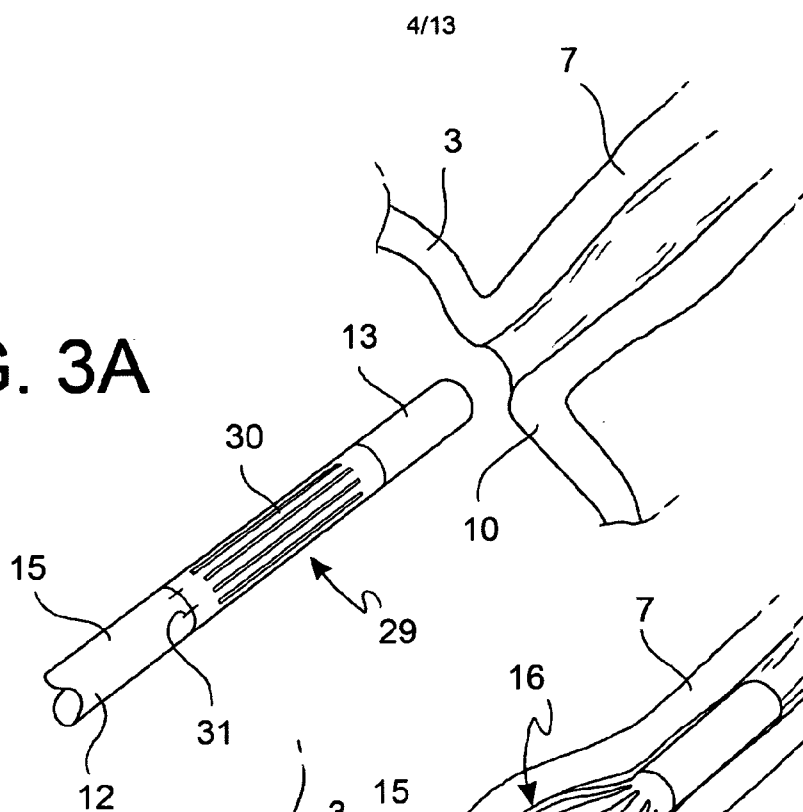


FIG. 3B

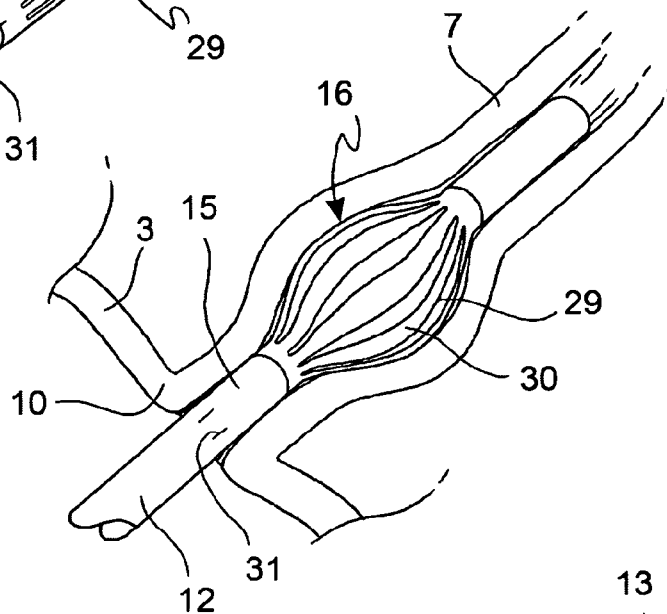
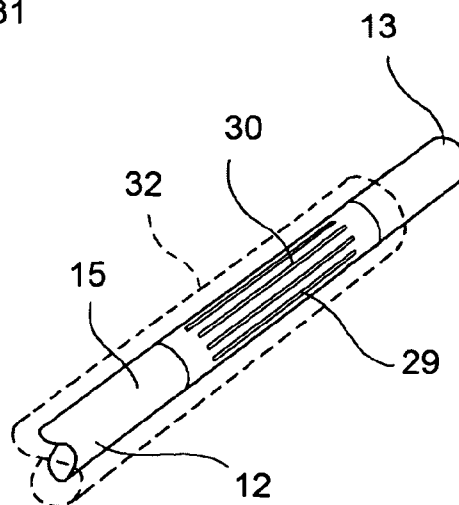
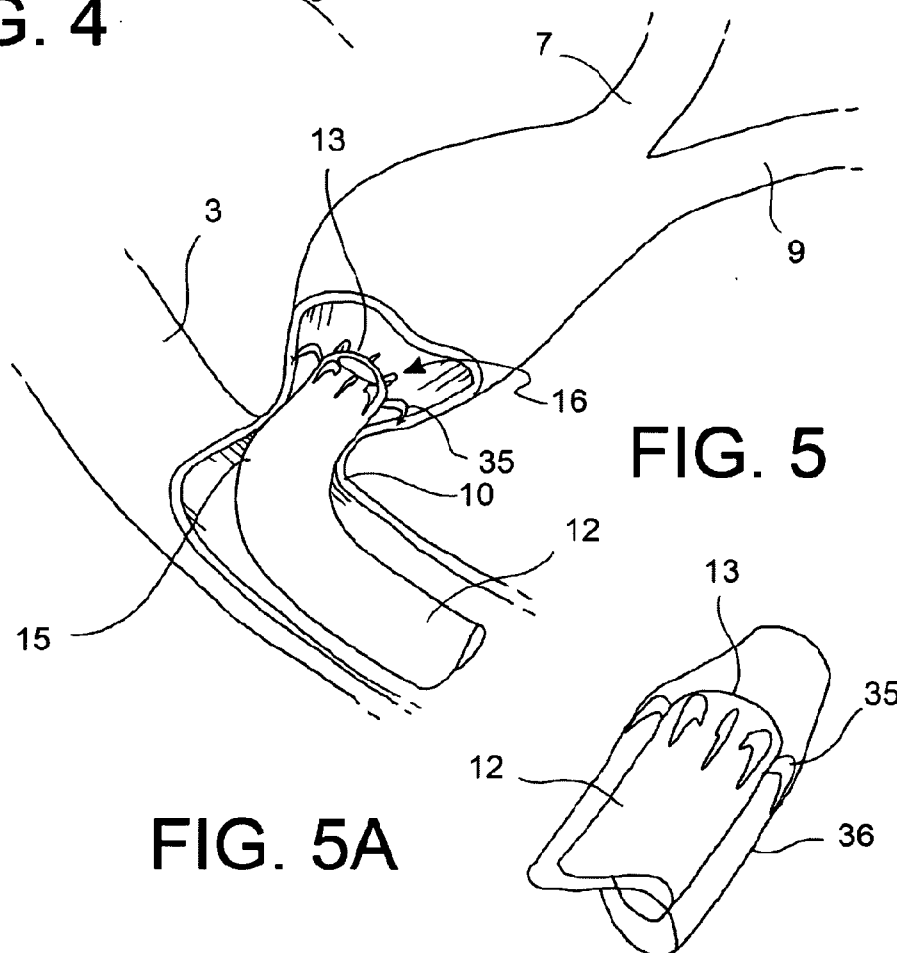
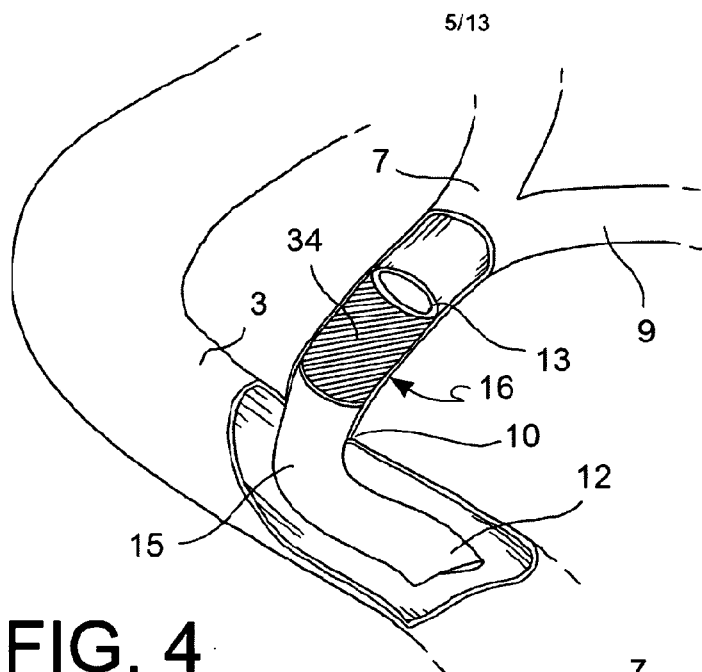


FIG. 3C





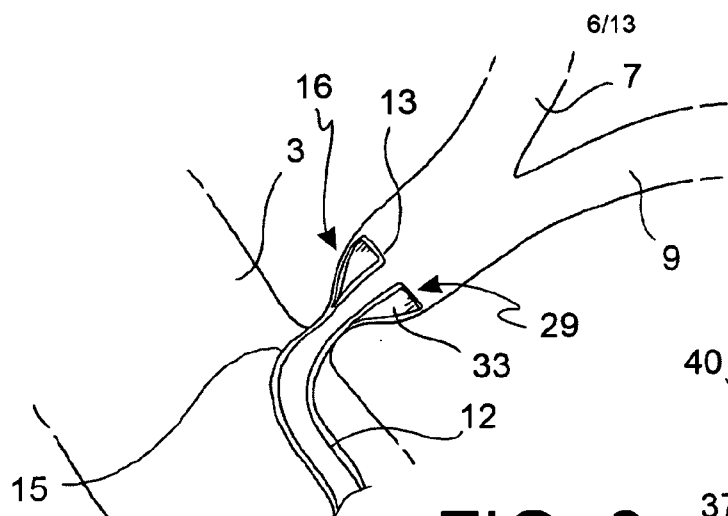


FIG. 6

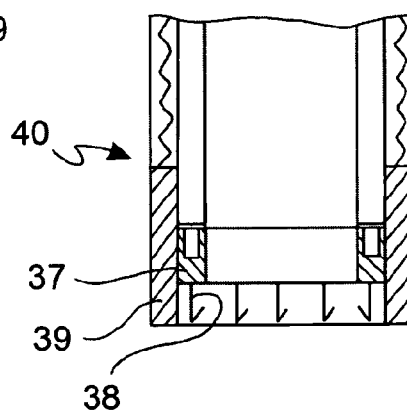


FIG. 7A

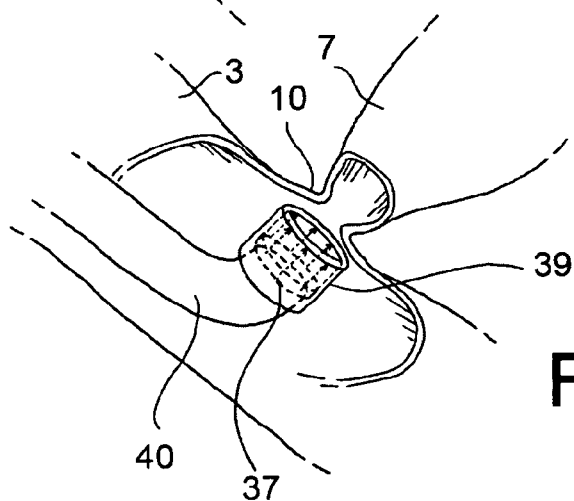


FIG. 7B

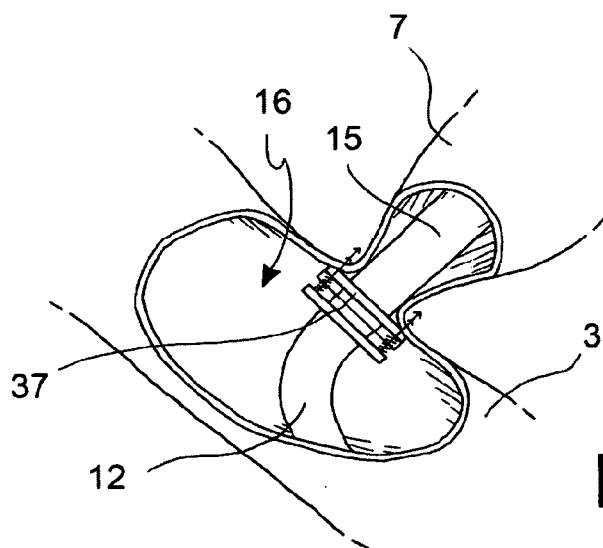


FIG. 7C

7/13

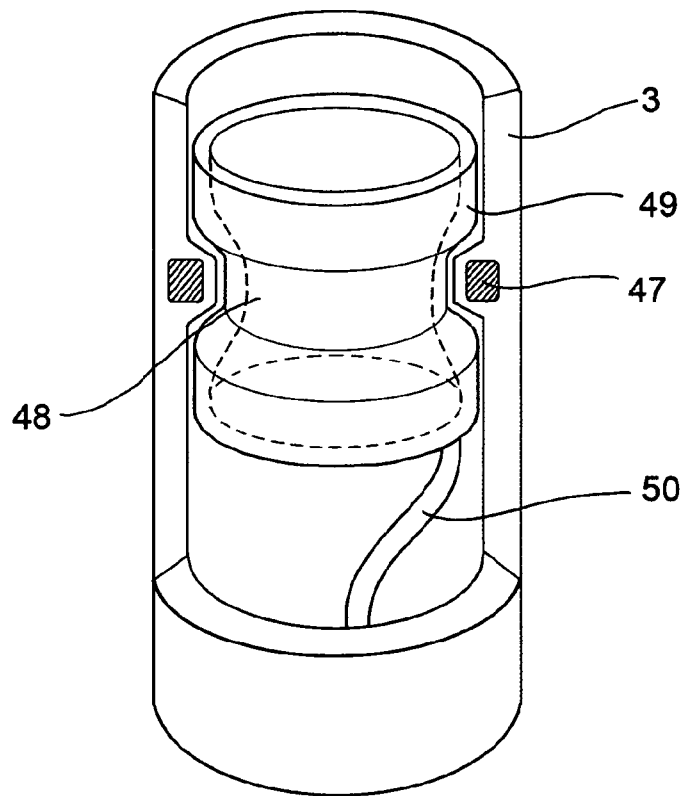


FIG. 8

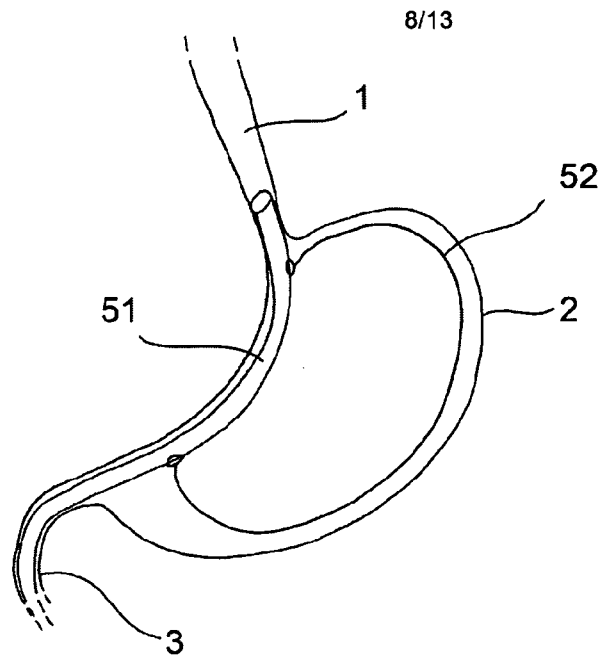


FIG. 9

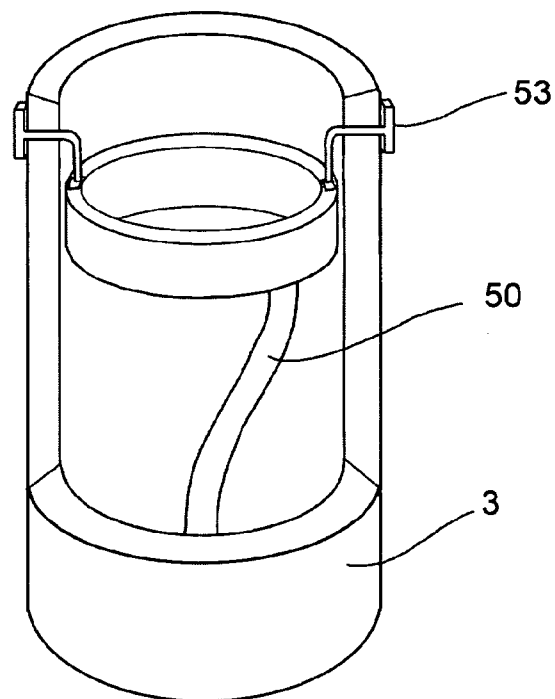


FIG. 10

9/13

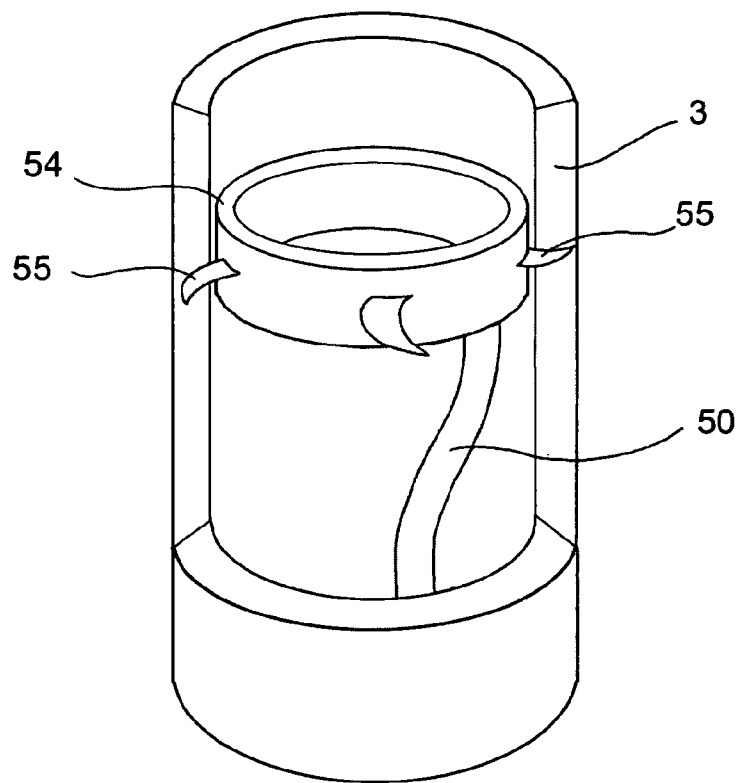


FIG. 11

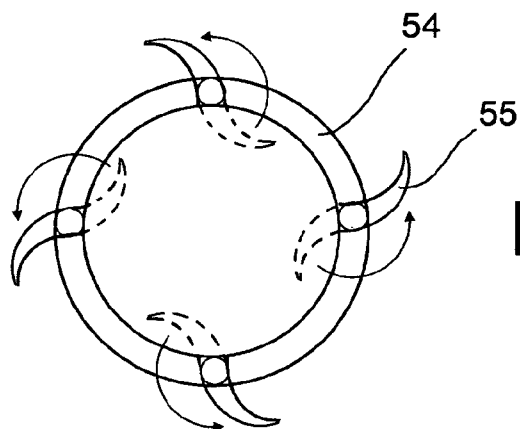


FIG. 11A



10/13

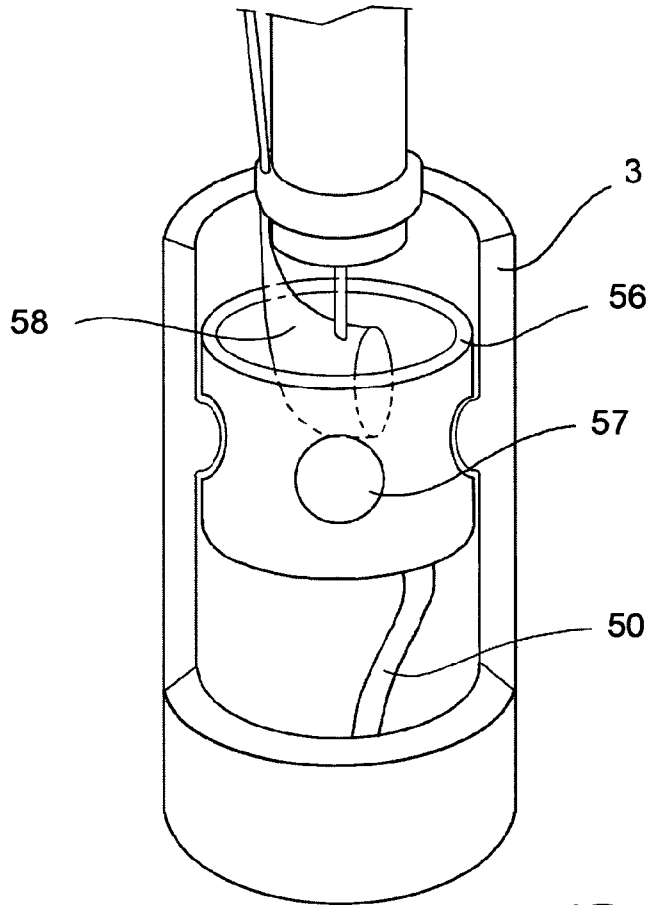


FIG. 12A

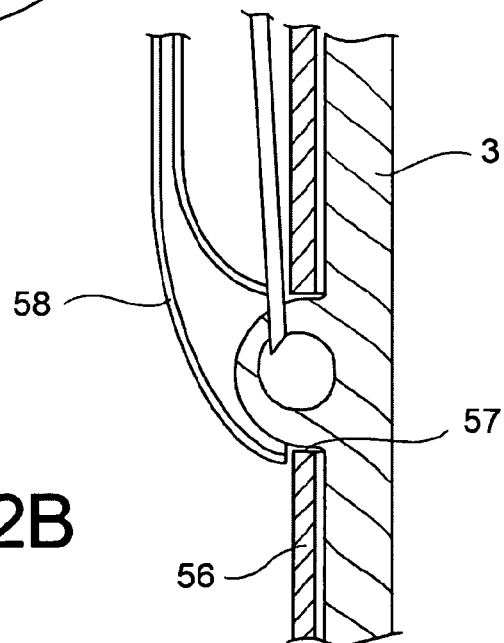
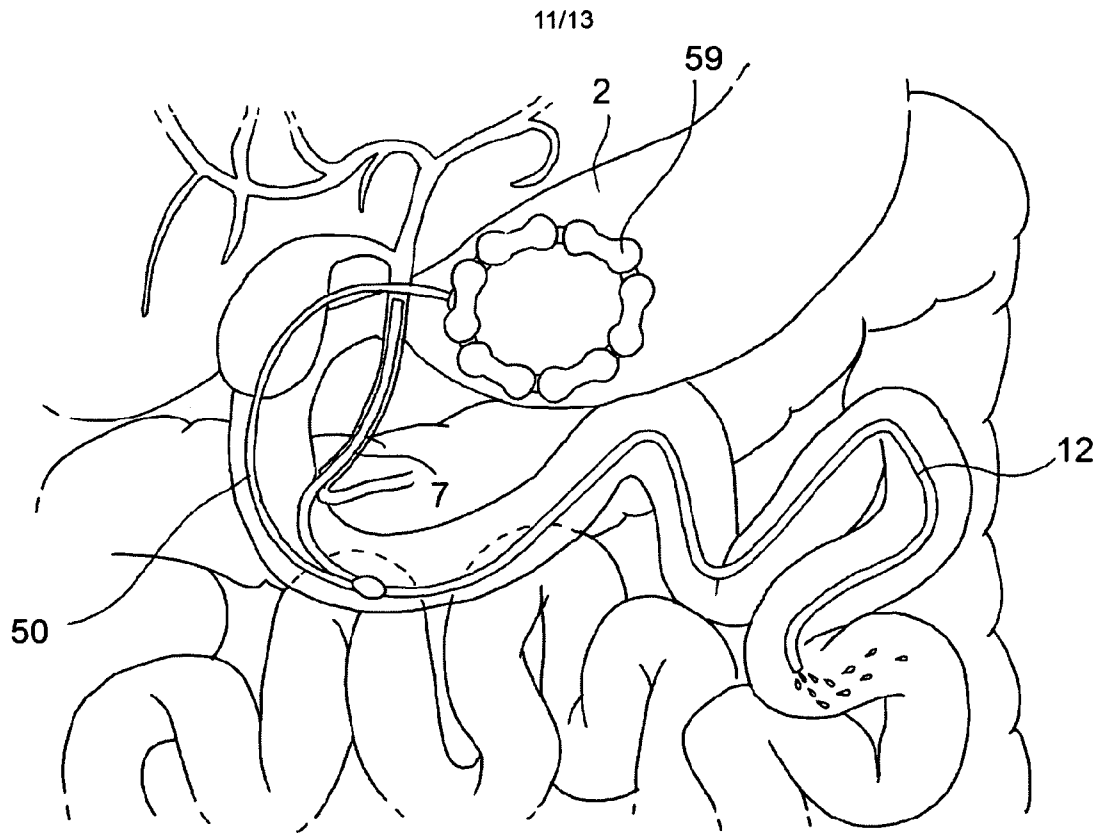
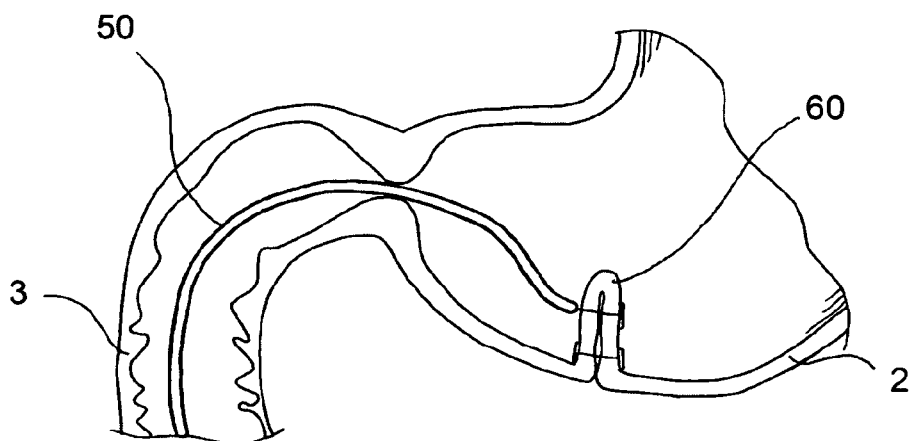


FIG. 12B



**FIG. 13**



**FIG. 14**

12/13

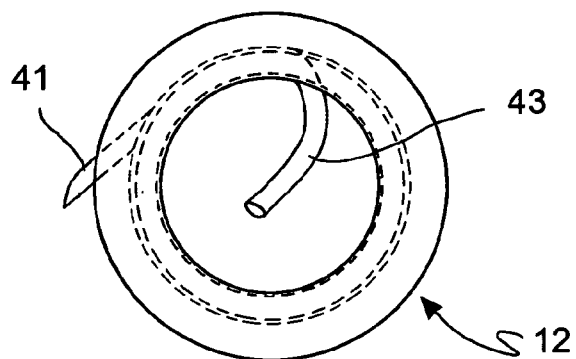


FIG. 15B

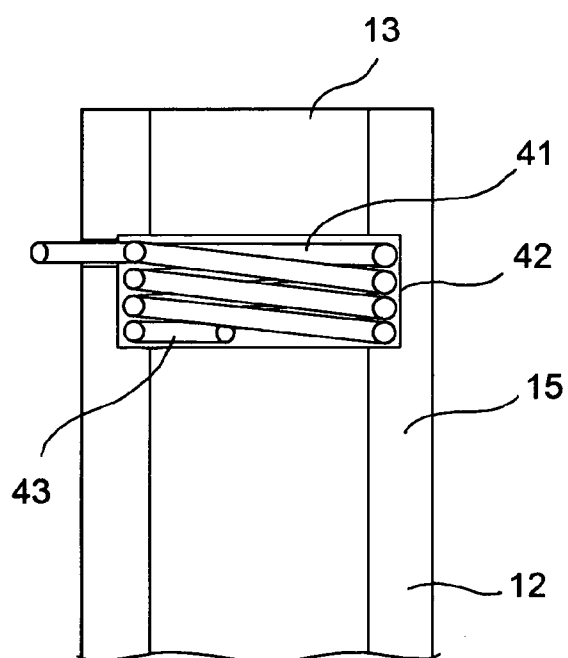


FIG. 15A

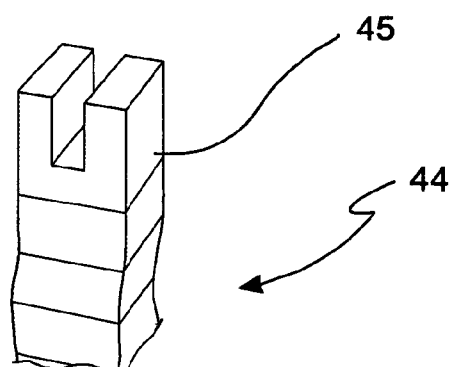


FIG. 15C

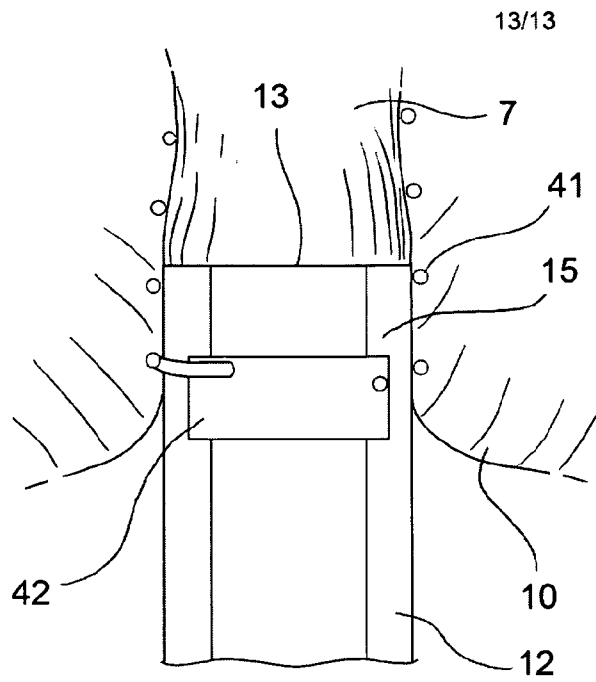
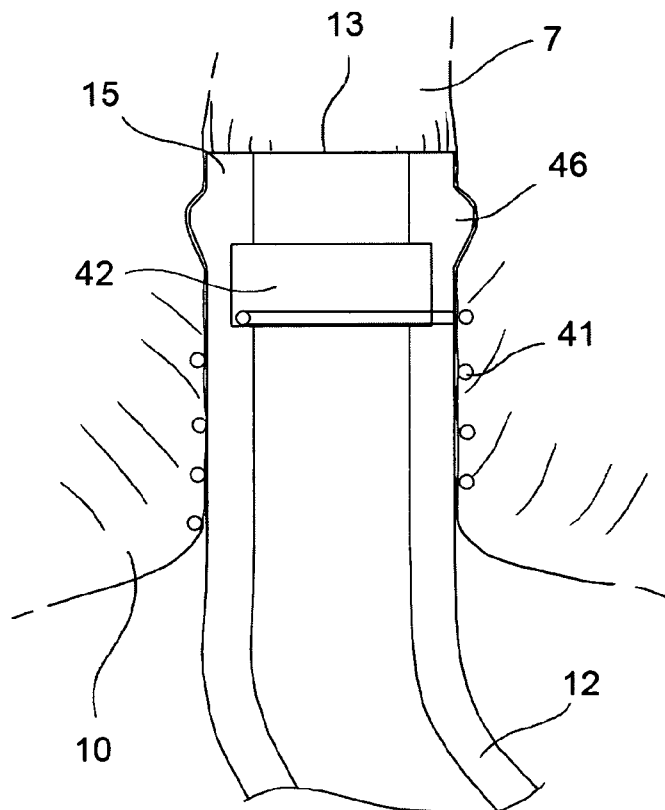


FIG. 15E



# INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2010/060285

A. CLASSIFICATION OF SUBJECT MATTER  
INV. A61B17/11 A61F5/00  
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	EP 1 508 312 A1 (ETHICON ENDO SURGERY INC [US]) 23 February 2005 (2005-02-23) paragraph [0020]; figure 3	1,2,24, 25 3,7,9, 10, 12-14, 16-22
X A	US 2004/249362 A1 (LEVINE ANDY H [US] ET AL) 9 December 2004 (2004-12-09) figures 2,7	1,24,25 2
Y A	US 2001/039425 A1 (DAKOV PEPI [US]) 8 November 2001 (2001-11-08) figure 12	3,7 4-6
Y A	US 6 802 847 B1 (CARSON DEAN F [US] ET AL) 12 October 2004 (2004-10-12) figures 50a,50b	3,7 4-6
	-/--	

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

\* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

4 February 2011

Date of mailing of the international search report

11/02/2011

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040,  
Fax: (+31-70) 340-3016

Authorized officer

Franz, Volker

# INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2010/060285

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2004/097992 A1 (SPENCE PAUL A [US] ET AL) 20 May 2004 (2004-05-20) figure 11a -----	1,3-7
A	US 2010/160847 A1 (BRAIDO PETER N [US] ET AL) 24 June 2010 (2010-06-24) figures 29,30 -----	1,3-7
X	US 2009/105733 A1 (COLEMAN JAMES E [IE] ET AL) 23 April 2009 (2009-04-23) figures 1,5,36 paragraph [0062] -----	1,8,11, 15
Y	US 2008/109069 A1 (COLEMAN JAMES E [IE] ET AL) 8 May 2008 (2008-05-08) figures 9a,9b -----	9,10
Y	WO 99/17680 A1 (LOCALMED INC [US]) 15 April 1999 (1999-04-15) figure 20a -----	12-14
A	US 2002/032487 A1 (DUA KULWINDER S [US] ET AL) 14 March 2002 (2002-03-14) figure 11 -----	1,8-15
Y	US 2007/239260 A1 (PALANKER DANIEL V [US] ET AL) 11 October 2007 (2007-10-11) paragraphs [0010], [0011] -----	16,17
A	US 2004/210282 A1 (FLOCK STEPHEN T [US] ET AL) 21 October 2004 (2004-10-21) paragraph [0098] -----	16,17
Y	EP 1 839 624 A1 (MEDTRONIC VASCULAR INC [US]) 3 October 2007 (2007-10-03) paragraph [0031] -----	18
A	WO 2009/126244 A2 (BIOABSORBABLE THERAPEUTICS [US]; HNOJEWYJ OLEXANDER [US]; RIVELLI PATR) 15 October 2009 (2009-10-15) figures 38a-38f -----	18
Y	WO 99/18887 A1 (VASCULAR SCIENCE INC [US]) 22 April 1999 (1999-04-22) figures 10a,23 -----	19-22
A	US 2002/049459 A1 (KATO YUKITOSHI [JP]) 25 April 2002 (2002-04-25) figure 18 -----	23

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/EP2010/060285

### Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 26-34  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☒ No protest accompanied the payment of additional search fees.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 2(completely); 1, 24, 25(partially)

Bile diversion conduit wherein the proximal end is bifurcated. This group of claims is directed towards solving the technical problem how to reduce the risk of obstruction of the ampulla of Vater.

---

2. claims: 3-7(completely); 1, 24, 25(partially)

Securing means comprising a clip for connecting the ampulla of Vater and the diversion conduit. This group of claims is directed towards solving the problem how to connect a sleeve without the need to enter the ampulla of Vater.

---

3. claims: 8-15(completely); 1, 24, 25(partially)

Securing means comprising an expandable section. This group of claims is directed towards solving the technical problem how to hold the ampulla of Vater open.

---

4. claims: 16, 17(completely); 1, 24, 25(partially)

Securing means comprising an RF conducting outer surface. This group of claims is directed towards solving the technical problem how to fix the sleeve without inserting further devices into the ampulla of Vater.

---

5. claims: 18(completely); 1, 24, 25(partially)

Securing means comprising a fixating agent dispenser on the proximal end of the conduit. This claim is directed towards solving the technical problem how to fix the sleeve with minimal effort.

---

6. claims: 19-22(completely); 1, 24, 25(partially)

Securing means comprising anchoring barbs. This group of claims is directed towards solving the technical problem how to easily and at the same time solidly connect the sleeve to the papilla of Vater.

---

7. claims: 23(completely); 1, 24, 25(partially)

Securing means comprising a helical anchor. This claim is directed towards solving the technical problem how to fix the sleeve in the most stable way.



FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

---

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2010/060285

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 1508312	A1	23-02-2005	AU 2004205166 A1 10-03-2005
		BR PI0403365 A 03-05-2005	
		CA 2477990 A1 20-02-2005	
		CN 1608685 A 27-04-2005	
		JP 2005066341 A 17-03-2005	
		MX PA04008119 A 01-07-2005	
		US 2005043817 A1 24-02-2005	
US 2004249362	A1	09-12-2004	AT 454864 T 15-01-2010
		EP 1610719 A2 04-01-2006	
		WO 2004087233 A2 14-10-2004	
US 2001039425	A1	08-11-2001	NONE
US 6802847	B1	12-10-2004	US 2004116945 A1 17-06-2004
US 2004097992	A1	20-05-2004	NONE
US 2010160847	A1	24-06-2010	WO 2010071676 A2 24-06-2010
US 2009105733	A1	23-04-2009	EP 2217155 A2 18-08-2010
		WO 2009052919 A2 30-04-2009	
		IE 20080680 A2 13-05-2009	
US 2008109069	A1	08-05-2008	WO 2008056342 A1 15-05-2008
WO 9917680	A1	15-04-1999	US 6926734 B1 09-08-2005
US 2002032487	A1	14-03-2002	NONE
US 2007239260	A1	11-10-2007	AU 2007245098 A1 08-11-2007
		CA 2647994 A1 08-11-2007	
		EP 2001404 A2 17-12-2008	
		JP 2009532093 T 10-09-2009	
		WO 2007126906 A2 08-11-2007	
US 2004210282	A1	21-10-2004	NONE
EP 1839624	A1	03-10-2007	US 2007233227 A1 04-10-2007
WO 2009126244	A2	15-10-2009	NONE
WO 9918887	A1	22-04-1999	AU 9031898 A 03-05-1999
		US 6451048 B1 17-09-2002	
		US 6074416 A 13-06-2000	
US 2002049459	A1	25-04-2002	NONE